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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,518	05/20/2004	Gregory D. Plowman	034536-1595	7215
22428	7590	11/16/2005	EXAMINER	
FOLEY AND LARDNER LLP			YAO, LEI	
SUITE 500			ART UNIT	
3000 K STREET NW			PAPER NUMBER	
WASHINGTON, DC 20007			1642	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/849,518

Applicant(s)

PLOWMAN ET AL.

Examiner

Lei Yao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,23,24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10,23,26 and 27 is/are rejected.
- 7) ☒ Claim(s) 24 and 28-29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/16/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed on 9/6/05 in response to the previous Non-Final Office Action (6/6/05) is acknowledged and has been entered.

Claims 1-9, 11-22, 25 have been cancelled. Claims 10, 24, and 26 have been amended. Claims 28-29 have been added. Claims 10, 23-24, 26-29 are pending and under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

The following office action contains NEW GROUNDS of rejection.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on /916/2004 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Rejections Withdrawn

1. The rejection of claims 10 11, 12, 24-25 under 35 USC § 102 as being anticipated by Ibanez et al., (US Patent NO: 5614609) or Ibanez et al., (WO 9612805) is withdrawn in view of the cancellation and amendments to the claims.
2. The rejections of claims 10-12 and 23-27 are rejected under 35 U.S.C. 112, first paragraph (enablement), because the specification, to make the invention commensurate in scope with the claims, is withdrawn in view of the cancellation and amendments to the claims.

Response to Arguments

Rejection under 35 USC § 112- Drawn to written Description

The rejection of claims 10, 23-24, 26-27, and 29 are rejected under 35 U.S.C. 112 first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record in the prior Office Action

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(6/6/05, page 2-4). New claim 29 is also rejected for the same reasons of record, because the claims are inclusive of genus of ALK-7 are at least 95% identical to the sequence of SEQ ID NO: 2, and a genus of Alk-7 polypeptides which minimally comprise the cytoplasmic domain of SEQ ID NO: 2. The claims encompass significant structural dissimilarity and functional diversity as compared to the ALK-7 protein (SEQ ID NO: 2).

The response filed 9/6/05 has been carefully considered but is deemed not to be persuasive. The response states that the claimed ALK-7 polypeptides are unified by significant structural similarity to the full-length ALK-7 protein and have an amino acid sequence that is at least 95% identical to that SEQ ID NO: 2. The response further states that a polypeptide meeting the requirement of 10-b will have an essential intact ALK-7 catalytic domain, and would be expected to have kinase activity. In response to these arguments, the instant claims are inclusive of a genus of ALK-7 polypeptides comprising an amino acid sequence that is at least 95% identical to the sequence of SEQ ID NO: 2. The claims encompass significant structural dissimilarity and diversity as compared to the ALK-7 protein (SEQ ID NO: 2), and its catalytic and cytoplasmic domains (193-485 and 137-493 of SEQ ID NO: 2). It is noted that recitation of the term "ALK-7" polypeptide does not imply a specific functional activity for said polypeptide. Therefore the genus of proteins encompassed by the instant claims includes polypeptides, which differ widely in both structure and function from SEQ ID NO: 2. It is known in the art that even a single modification or substitution in a protein sequence can alter the protein function. Protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, the replacement of a single lysine at position 118 of the acidic fibroblast growth factor by aspartic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (Burgess et al, Journal of Cell biology, Vol 111, p2129-2138, 1990).

Although drawn to DNA arts, the finding in University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) is relevant to the instant claims. The Federal Circuit addressed "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or

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of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.”

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., ___ F.3d ___, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of ALK-7 polypeptides that are 95% identical to the SEQ ID NO:2 or to its catalytic domain, nor does it provide a description of the polypeptide have same catalytic functions as ALK-7 of SEQ ID NO:2. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of polypeptides that are 95% identical to the SEQ ID NO: 2 is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Therefore, only the ALK-7 protein comprising of a full length amino acid sequence SEQ ID NO: 2, a polypeptide consisting of a catalytic domain of 193-485 of SEQ ID NO:2, and a polypeptide consisting of a cytoplasmic domain of 137-485 of SEQ ID NO:2, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

The following is a New Ground of rejection

Claim Objections

Claims 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Therefore, NO claim is allowed.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

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KAREN A. CANELLA PH.D.
PRIMARY EXAMINER